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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,820	08/07/2003	Philip Chidi Njemanze		7656

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/635,820	NJEMANZE, PHILIP CHIDI	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

APPLICANT'S INVENTION

1. Applicant's invention is directed to receptor mediated nanoscale copolymer assemblies for diagnostic imaging and therapeutic management of hyperlipidemia and infectious diseases.

Note: Claims 1-20 are pending.

APPLICANT'S ELECTION

2. Applicant's election of Group II (claims 9-13) in the reply filed on 10/25/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Thus, the restriction requirement is still deemed proper and is therefore made FINAL.

In addition, the Examiner acknowledges Applicant's election of the species wherein the hydrophilic agent is a cytokine; the hydrophobic active agent is an antiviral agent; the tissue specific agent is an antibody; the therapeutic agent is a vaccine; the target cell use nucleosides; and the infectious disease is a viral disease. The search was not further expanded because prior art was found to render obvious Applicant's elected species.

WITHDRAWN CLAIMS

3. Claims 1-8 and 14-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

112 SECOND PARAGRAPH REJECTIONS

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 13: the claims are ambiguous because of the phrase 'specific, non-limiting examples of suitable hydrophobic active ingredients may be selected from' is improper Markush terminology. Applicant is respectfully requested to review MPEP 803.02 for acceptable Markush terminology.

Claim 12: the phrase 'can be' is improper Markush terminology. Applicant is respectfully requested to review MPEP 803.02 for acceptable Markush terminology.

103 REJECTIONS

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbell (Science, 4/25/2003, Vol. 300, No. 5619, pages 595-596 in view of Todd et al (US Patent No. 6,555,654).

Hubbell discloses the enhancing of drug function that involves the method of associating the drug with a polymeric carrier and designing various domains of the polymer to deliver drugs to a particular compartment within the cell. The study partitioned a hydrophobic drug within the core of a micelle formed by self-assembly of an AB block copolymer. The hydrophobic B domain self-associates into a core to escape contact with water, pushing the hydrophilic A domains into a corona surrounding the core. This yields spherical micelles. Micelles are particularly attractive for drug delivery because they do not require the chemical identity of the drug. The drug may be loaded into the core of the micelle. The administration of micelle-incorporated drugs achieves several positive effects. On the level of the whole body, the drug is solubilize, avoiding use of the hydrophobic carriers usually used to deliver the drugs. On the level of the tumor and its metastases, the leakiness of the tumor blood vessels allows the colloidal particles to accumulate in the tumor. The micelle incorporated small hydrophobic drug may enter the cytoplasm at a high rate by diffusing across the endosomal membrane (see entire document, especially, abstract). Hubbell discloses that Kataoka et al formed polymer micelles with hydrophobic cores chemically bound (grafted) to the anticancer drug adriamycin (pages 1-2, bridging paragraph). Diffusion across the membrane is possible as a result of the drug's hydrophobicity (page 2, first complete paragraph). Nanoscale polymer assemblies are developed for the delivery of

plasmid DNA to the cytoplasm (page 2, fifth complete paragraph). Cell surface binding ligands may be graphed to the tips of the chains forming the corona leading to enhanced cellular uptake (page 2, sixth complete paragraph). Mechanisms have also been developed to disrupt the endosomal membrane. Peptides that induce fusion or lysis of membrane vesicles may be incorporated into nanoscale assemblies. The amphiphiles then destabilize the endosomal membrane to allow permeation of the incorporated drug (pages 2-3, bridging paragraph). The micelle-mediated mechanisms involve endocytosis and subsequent endosomal permeation of destabilization. Some proteins including the HIV TAT protein contain protein transduction domains that cause the parent protein to cross the membrane directly. Attachment of such peptides to oligonucleotides and proteins induces their direct transport across the membrane in a manner. While Hubbell discloses Applicant's elected invention broadly, the reference fails to disclose all components of Applicant's elected species.

Todd et al disclose methods of treatment of diseases in which the gene may be implicated including autoimmune diseases, diseases and disorders involving disruption of endocytosis, and/or diseases and disorders involving cytokine clearance and/or inflammation, and viral infection (see entire document, especially, abstract; column 24, lines 24-33). Possible cytokines include interleukin-1 beta, interleukin-2, and interleukin-6 (column 10, lines 64-68; column 11, lines 5-10). Nucleic acids may be utilized. When a nucleic acid is intended for use in a polymerase chain reaction, one or more nucleosides may be utilized (column 18, lines 51-60). The screening for the presences of one or more substances in a sample has diagnostic and/or prognostic use

(column 23, lines 30-33). Various modulators of polypeptides may be utilized. A method of screening for a substance which modulates activity of a polypeptide involves testing the activity of the treated polypeptide and comparing that activity with the activity of the polypeptide in comparable reaction of the test substance or substances (column 24, lines 40-46). Following identification of a substance that modulates or affects polypeptide activity, the substance may be further investigated further (column 24, lines 60-65). After the pharmacophore has been identified, it structure is modeled according to its physical properties using data from a range of source including spectroscopic techniques, x-ray diffraction data, and NMR (column 25, lines 38-45). Various systems may be used for cloning and expression of a polypeptide. Suitable host cells include bacteria, eukaryotic cells, and baculovirus systems (column 26, lines 17-18 and 47-58). Another aspect of the invention of Todd et al disclose an antibody that is ale to bind specifically to the polypeptide (column 28, lines 19-37). Targeting therapies may be used to deliver the active agent more specifically to certain types of cell by the use of targeting systems such as antibody or cell specific ligands (column 34, lines 39-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Hubbell using the teachings of Todd et al and generate a method and system for improving diagnostic imaging and/or delivering therapeutically active agents used I controlling infectious diseases because Hubbell et al disclose the overall procedure for enhancing drug function in order to deliver drugs to a particular compartment within a cell and Todd et al discloses specific components (i.e., antiviral agent, cytokine, antibody, and vaccine) that may be utilized in the

treatment of infectious diseases. Thus, since both Hubbell and Todd et al are directed to delivering therapeutic agents to a desired target, the references may be considered to be within the same field of endeavor. Hence, the teachings of the references are combinable.

SPECIFICATION

8. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT

(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer

program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or

REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(f) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Note: Applicant is respectfully requested to follow the order that is recommended and listed above. Applicant should not incorporate any information that was not part of the original specification; otherwise, it is new matter.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1618

January 6, 2006